Remarks

Claims 25-46 are pending in the present application. Claims 25, 30 and 45 have been amended. Claim 46 has been newly added.

Claim 25 has been amended to recite a receptacle having a proximal end and a distal end, comprising: an outer wall and an inner wall fixed relative to said outer wall, said outer wall and inner wall together defining an annular portion therebetween; and an inner space defined by said inner wall open at each of said proximal end and said distal end, enabling passage of fluid via said inner space whilst holding said liquid within said annular portion.

Likewise, claim 30 has been amended to recite in part "providing a receptacle having an outer wall and an inner wall fixed relative to said outer wall, said outer wall and inner wall together defining an annular portion therebetween."

Claim 45 has been amended to recite in part "a receptacle comprising an outer wall and an inner wall fixed relative to said outer wall, said outer wall and inner wall together defining an annular portion therebetween."

New claim 46 recites "the receptacle according to claim 25, wherein the inner wall is securely fixed in place within the receptacle and configured sufficient to prevent said inner wall from longitudinal movement with respect to said outer wall."

Support for amended claims 25, 30, and 45, and new claim 46, can be found throughout the specification, Figures, and claims as originally filed, for example, in

Figures 1-3. Figures 1-3 show the receptacle 10 having inner wall 14 and outer wall 12 where the inner wall is fixed relative to the outer wall. See also the side view of the receptacle shown in Figures 4A and 6.

No new matter has been added.

The Examiner is thanked for conducting a telephone interview with the undersigned attorney.

Submitted herewith is an unofficial English translation of the Robert Cassou reference, FR 2574919.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 25-26 and 28-45, have been rejected under 35 USC § 102(b) as being anticipated by Robert Cassou.

The Examiner asserts that Cassou et al. meets the limitations of claims 25-26 and 28-45.

In view of the following, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.,* 9 USPQ2d

1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

Present claims 25, 30, and 45 have been amended to recite a receptacle having or comprising "an outer wall and an inner wall fixed relative to said outer wall, said outer wall and inner wall together defining an annular portion therebetween."

Applicants thank the Examiner for indicating during the telephone interview with the undersigned attorney that the claims would appear allowable if amended to recite a receptacle where the inner wall is fixed relative to the outer wall.

As can be seen from the figures of Cassou et al. and the unofficial English translation, Cassou et al. describes a vessel comprising a tubular jacket 1 blocked off at either end by a plug 3 whose center integrates an orifice 4 through which a tube 2 can be passed. The tube 2 is mobile when it is translated in the flexible blanking plugs. This mobility is necessary to allow filling of the tube. More specifically, Cassou et al. requires that tube 2 be ***mobile*** within the tubular jacket.

Cassou et al. requires the use of a filling device to facilitate introduction of material into the tube. The filling device includes an extension 6 having a nozzle 11 in the form of a needle which needs to match the inner diameter of the elastic plug 3 such that upon insertion of the nozzle into the vessel the tube 2 is pushed

axially inside the jacket 1. The material is then introduced into the jacket via a specified (radial expulsion) orifice 10 once inside the tubular jacket.

In contrast, the presently claimed receptacle permits the mere introduction of material via opening 24 at the proximal end 26 which is then sealed by suitable sealing means, such as a plug 30 or a plug 46, etc. Specialized equipment is not required and the material may be introduced into the annular portion by the use of conventional devices, for example, pipetting devices.

Applicants assert that Cassou et al. does not teach or suggest a receptacle having or comprising "an outer wall and an inner wall fixed relative to said outer wall, said outer wall and inner wall together defining an annular portion therebetween" as presently claimed.

Further, Applicants note that the use of the filing device of Cassou et al. raises some risks involved with the operation of the device. For instance, improper use of the device may result in breakage of the nozzle within the vessel, undesired pressure within the vessel upon introduction of the material, contamination of the vessel by reintroduction of the material, contamination of the vessel by reintroduction of the portion of the inner tube that was exposed during filling, etc.

Cassou et al. also provides a disposable vessel for a single use. The thawed material is retrieved by "cutting the tubular jacket 1 in the area ("d")" (see page 4, line 40, of the English translation). The alternative means for retrieving

the material includes application of pneumatic pressure through the inner tube (after partial removal of the inner tube) thus causing the material to be expelled through the orifice in the opposite plug (see page 4, line 45, to page 5, line 7, of the English translation). This may allow the tube to be reused, but the tube would be difficult to clean.

The present receptacle is a multi-purpose device which allows the simple expulsion of the thawed material from within the annular portion, for example, by simply removing the plug and the distal end. Thus, the present receptacle provides a simple, multi-purpose device for temperature change and other manipulations of liquid samples inserted therein.

In view of the foregoing, it is submitted that Cassou et al. does not teach each and every element of the presently claimed invention because Cassou et al. does not teach or suggest a receptacle having or comprising "an outer wall and an inner wall fixed relative to said outer wall, said outer wall and inner wall together defining an annular portion therebetween" as recited in the present claims. In complete contrast, Cassou et al. ***requires*** that tube 2 be mobile relative to the tubular jacket.

Accordingly, it is submitted that Cassou et al. does not teach each and every element of claims 25-26 and 28-45 as required for anticipation under 35 USC § 102. Thus, the Examiner is respectfully requested to withdraw this rejection.

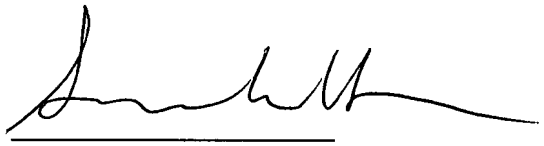
Conclusion

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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Titles:
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Vessel for freezing and defrosting living substances

The invention relates to a vessel for freezing and defrosting living substances, particularly microorganisms, cells, tissues, viruses, blood, semen and embryos. The vessel is characterized in that it is constituted by a tubular jacket 1 that is blocked off at either end by a flexible and elastic plug 3 whose center integrates an orifice 4 through which a tube can be passed that is coaxial at the tubular jacket and in which the freezing or defrosting agent circulates, whereby said tube 2 is mobile when it is translated in flexible blanking plugs, thus allowing for a hookup with a filling device consisting of an extension 6 that is hooked up to a source of semen that is to be conditioned, whereby said extension integrates a nozzle 11 in the form of a needle which is inserted in one end 3 of said mobile tube 2, whereby said extension integrates a radial expulsion orifice 10 that is placed inside the tubular jacket 1 when said tube 2 is moved axially inside said jacket.

Vessel for freezing and defrosting living substances

The invention relates to vessel that is specially made for the homogenous and optimized freezing and defrosting of living substances, particularly microorganisms, cells, tissues, viruses, embryos and animal semen.

The vessels that are currently used for cryogenic preservation of living substances, and particularly animal semen, resemble drinking straws made of extruded plastic. These vessels are blocked off at one end by a moveable blanking plug that acts as a piston head. After the frozen substance in the vessel is defrosted, the substance is expelled at the end opposite the blanking plug via one or more expulsion orifices.

These straws have been highly successful for several decades, with millions sold, because they are ideal for freezing and defrosting small volumes of material ranging from 0.25-0.50 cc. However, these straws would probably not be suitable for applications involving other animal species such as pigs or horses owing to the fact that such animals require far larger amounts of semen. This would mean that the capacity of these devices would have to be greatly expanded, and this in turn would result in heterogeneous freezing and defrosting.

In such a case, the thermal gradient would be inadequate from a physics standpoint owing to the fact that when immersed in liquid nitrogen at minus 196 °C, the edge of the straw would freeze more quickly than the interior of the straw since the edge is more exposed. This type of gradual freezing that begins at the edge of the straw and moves inward toward its center could cause some or all of the cells in the straw to explode, which would result in a high mortality rate. Moreover, this same phenomenon would occur during the defrosting process since the defrosting would also be gradual, and when immersed in 34 °C water, the edge of the straw would defrost first and the column of semen would only be reactivated later.

Hence the invention is characterized in that the vessel is composed of a tubular jacket that is blocked off at either end by a flexible and elastic blanking plug that has an orifice in the middle through which a tube can be passed that is coaxial at the tubular jacket and in which the freezing or defrosting agent circulates, whereby said tube is mobile when it is translated in flexible blanking plugs, thus allowing for a hookup with a filling device consisting of an extension that is hooked up to a source of semen, whereby said

extension integrates a radial expulsion orifice 10 that is placed inside the tubular jacket 1 when said tube 2 is moved axially inside said jacket.

Hence the coaxial tube has two functions: it serves as a conduit for the thermal agent (which can be a liquid or gas) for purposes of filling the vessel (thanks to the tube's compatibility with the nozzle extension) and it stoppers one end of the vessel when the filling process has been completed and the tube has been reinserted into the two flexible blanking plugs that act as pitch pockets.

The invention will be better understood, and other advantages and characteristics which it exhibits will emerge better on reading the description which follows, made with reference to the attached drawings, in which -

Figure 1 is a cutaway axial and longitudinal view of the vessel according to the invention;

Figure 2 is a top view of the filling device for the vessel;

Figure 3 is a longitudinal cutaway view of the filling device its operating position.

As can be seen in Figure 1, the vessel according to the invention is essentially composed of an external tubular jacket 1, a narrow tube 2 that extends coaxially to the external jacket 1, and two blanking plugs 3 made of flexible and elastic material and which act as pitch pockets.

The tubular jacket 1 can be composed of a tube made of transparent extruded plastic and is constituted by, for example, a cylindrical element. The main purpose of the tube 2 is to carry the thermal agent, whereby said tube is slightly narrower than the jacket 1, can be made of extruded plastic and can have a cylindrical profile. Preferably this tube should be colored so that various species and breeds can be differentiated from each other, and so that the nature of the substance inside the tubular jacket can be identified. A realization in colors would also allow for synoptic color coding of the product inside the vessel. In addition, lettering or the like could be printed on the tubular jacket or coaxial tube, or an identification sleeve could be threaded onto or attached to the external end of the coaxial tube. The advantage of printing lettering or the like on the coaxial tube and realization of a transparent external jacket is that the nature of the substance inside said jacket could be identified easily, whereby said substance would remain tamper proof within said jacket.

The colored sleeves 3 glued to either end of the tubular jacket 1 have an orifice 4 at their center, whereby said orifice is slightly narrower than the coaxial tube 2, thus allowing for insertion of said tube into the tubular jacket, whereby the orifice 4 also serves to radially expand the blanking plug 3 upon insertion thereof, whereby the elasticity of said blanking plug causes it to tighten radially against the tube such that said blanking plug abuts the tube such that a watertight seal is created along the entire periphery of the plug.

This coaxial structure of the vessel has an impact on the freezing properties at the periphery and in the center since said structure makes it possible to immerse the entire vessel in the freezing agent and to hook up at least one of the two ends of the coaxial tube 2 (via flexible tubes) to an external source of thermal fluid, whereby the nature and temperature of said fluid can either be identical to and/or different from that of the fluid in which the vessel 1 is immersed In addition, the thermal effect can be leveraged through the use of two coaxial tubes 2 of differing diameters or thicknesses. It in fact emerges that (a) the wider the diameter of the tube 2, the greater the external freezing or heating surface; and (b) the thicker the tube 2, the weaker the thermal effect.

The cylindrical enclosure comprised between the coaxial tube 2 and the tubular jacket 1 is filled by means of a device of the type shown in Figure 2, whereby said device

comprises a long shaft 6 one of whose ends integrates a hose coupler 7 that is hooked up to a source containing a living substance. This shaft 6 acts as an extension, whereby its diameter is slightly smaller than the internal diameter of the coaxial tube 2, thus enabling said shaft to be inserted into one of the ends of said tube until said shaft abuts said tube thanks to the conical shoulder 8 that is realized on the edge of said shaft. This filling device has a tubular segment 9 that communicates with the hose coupler 7, whereby said hose coupler is the end point of a radial orifice 10 that allows for expulsion of the substance that is inside the vessel's cylindrical enclosure 5.

The vessel is very easy to fill since it suffices to insert the extension 6 in the end of the coaxial tube 2 and then push the extension/tube assembly toward the tubular jacket until the expulsion orifice 10 on the filling device is itself inside the vessel, as shown in Figure 3. At this stage, mere delivery of the substance causes it to be distributed in the tubular chamber 5 since there is no obstruction that could prevent said substance from flowing freely. In this regard, it should be noted that the shaft 6 or extension is long enough to traverse the coaxial tube 2, thus enabling said shaft or extension to serve as a guide for said tube when said tube is displaced vis-à-vis the external jacket 1. In this case, the packing coefficient of the blanking plugs that act as pitch pockets is not great enough to prevent the coaxial tube 2 from sliding, thus allowing for the filling of the vessel as described above. The filling device integrates a substance expulsion orifice 10 and a fume stack in the form of needle that is welded along one of the reinforcing elements of the shaft 6, whereby said stack allows for expulsion of the air contained in the cylindrical enclosure 5, thus allowing for the filling of said enclosure. During the filling operation, care must be taken to ensure that the orifice 10 is positioned at distance "d" from the sleeve 3 in such a way that an air cushion remains into which semen can expand during the freezing and defrosting processes.

When the filling process has been completed, the coaxial tube is returned to its original position by simultaneously grasping (a) the opposite end of the tube; and (b) the extension 6 such that the end 2 of the tube is pushed outside the tubular enclosure 1. This movement is made possible by the fact that the extension shaft 6 retains and guides the coaxial tube while it is being moved. Once the tip 2_1 has moved to the other side of the blanking plug and is outside the vessel, the operator disconnects the filling device, whereupon the tube 2 can also be used as a feed line for thermal fluid.

This new type of conditioning is particularly advantageous for two reasons: (a) it allows for preservation of a larger amount of material; and (b) it allows for optimized and homogeneous freezing and defrosting of the entire mass of the substance being treated, while at the same time also enabling (if necessary) programmed and differentiated freezing and defrosting processes by varying the diameter or thickness of the coaxial tube 2. This type of vessel could be used to preserve any other type of living substance such as cells, viruses, bacteria, blood, semen, and the like.

Following defrosting, the reactivated substance is retrieved by simply cutting the tubular jacket 1 in the area ("d") containing the air cushion, and then cutting said jacket at the opposite end, thus allowing the contents of the vessel to be decanted into a receptacle from which the substance can be removed for purposes of artificial insemination or subsequent treatment, using a probe or pipette.

The contents of the vessel can also be retrieved by using the coaxial tube 2 to introduce a compressed fluid such as air, which will then act as a pneumatic piston such

that the substance is expelled through one of the two blanking plugs. If this method is used, it suffices to extract almost the entire length of the tube 2 of the tubular jacket 1 such that, after having been removed, the internal tip of said tube is positioned in one of the blanking plugs 3, whereby the tubular jacket becomes the sole chamber. The introduction of compressed air into the coaxial tube 2 pushes the substance through the orifice of the opposing blanking plug 4, which is now empty by virtue of said tube 2 having been removed.

According to another embodiment of the invention, a coaxial tube 2 made of biodegradable material (known to the state of the art) could be realized, and then used to condition another substance that is mixable with the substance stored in the cylindrical chamber 5 that is located between the tubular jacket 1 and said tube 2. In this case, both ends of the coaxial tube 2 would be blocked off, which would allow for progressive degradation of the internal tube under predefined time and temperature conditions, thus allowing for admixing of the two products contained in the two coaxial chambers

CLAIMS

1). Vessel that is used to freeze and defrost living substances, particularly microorganisms, cells, tissues, viruses, and animal semen and embryos, characterized in that said vessel is composed of a reservoir constituted by a tubular jacket 1 that is blocked off at either end by a flexible and elastic blanking plug 3 whose center integrates an orifice 4 that allows a tube 2 to be passed through the blanking plug 3, whereby said tube is preferably coaxial to the tubular jacket, whereby the freezing and defrosting agent circulate within said vessel.

2). Vessel that is used to freeze and defrost living substances according to claim 1, characterized in that the coaxial tube 2 is mobile when inserted in a flexible blanking plug 3, thus allowing a filling device to be hooked up to the vessel, whereby said filling device is composed of an extension 6 that is hooked up to a substance source and integrates a nozzle in the form of a needle which is inserted in one end of the mobile tube, whereby said extension integrates a radial expulsion orifice 10 that is placed inside the tubular jacket 1 when said tube 2 is moved axially inside said jacket.

3). Vessel that is used to freeze and defrost living substances according to claim 1, characterized in that the diameter of the nozzle extension 6 is the same as that of the coaxial tube 2, thus allowing said extension to slide freely in the flexible blanking plug 3 of the tubular jacket 1, whereby said nozzle integrates an air inlet 11 composed of a small needle-like stack that allows for expulsion of the air in the tubular jacket 1 when said jacket is filled.

4). Vessel that is used to freeze and defrost living substances according to claim 2, characterized in that the radial filling orifice 10 realized on the nozzle extension 6 is positioned inside the tubular jacket at a defined distance from the flexible blanking plug 3, such that an expansion air cushion is maintained in said jacket 1 after jacket 1 is filled.

5). Vessel that is used to freeze and defrost living substances according to claim 1, characterized in that the tubular jacket 1 and the tube 2 that is coaxial to said jacket 1 are both cylindrical elements.

6). Vessel that is used to freeze and defrost living substances according to claims 1-5, characterized in that the coaxial tube 2 is hooked up to a fluid source that ensures that the contents of the tubular jacket freeze and defrost from the center, and coterminously with or following the thermal shock that is exerted on the external periphery of said jacket.

7). Vessel that is used to freeze and defrost living substances according to claims 1-6, characterized in that the thermal impact of the freezing or defrosting agent can be modified by varying the temperature and/or throughput of said agents or by modifying the diameter or thickness of the coaxial tube.

8). Vessel that is used to freeze and defrost living substances according to claims 1-7, characterized in that the external jacket 1 is made of transparent plastic that can be realized with or without an imprint.

9). Vessel that is used to freeze and defrost living substances according to claims 1-8, characterized in that the coaxial tube 2 is colored and can be realized with or without an imprint, whereby said color allows for synoptic identification such that species or breeds corresponding to the conditioned substance can be differentiated.

10) Vessel that is used to freeze and defrost living substances according to claims
1-9, characterized in that the coaxial tube 2 is hooked up to a source of thermal fluid by a flexible tube.

11) Vessel that is used to freeze and defrost living substances according to claims 1-10, characterized in that the substance contained in the cylindrical chamber 5 comprised between the coaxial tube and the tubular jacket 1 is retrieved by cutting the two ends of said tubular jacket.

12). Vessel that is used to freeze and defrost living substances according to claims 1-10, characterized in that the substance contained in the tubular chamber 5 is retrieved by retracting the coaxial tube 2 so as to allow for removal of virtually the entire tubular jacket 1, whereby a compressed fluid is introduced into said tube, resulting in expulsion of the substance contained in said jacket, via the orifice 4 in the blanking plug 3 that is empty by virtue of said tube 2 having been removed.

13) Vessel that is used to freeze and defrost living substances according to one of claims 1-12, characterized in that the axial tube 2 is made of a biodegradable material and contains a substance that mixes with the substance in the cylindrical chamber 5, thus allowing for admixing of the two substances under predetermined temperature and time conditions.